

developed a right SIRVA as a result of the Tdap vaccine she received on November 6, 2017. Pet. at 1.

After carefully considering the evidence presented in this case, to include the medical records, expert opinion, and affidavits, I find that Petitioner received the Tdap vaccination in her right arm and that her shoulder pain began that same day.

I. Procedural History

Petitioner filed her petition on October 31, 2018. Pet., ECF No. 1. Petitioner filed supporting medical records and affidavits on November 2, 2018. Exs. 1-10.

Respondent filed his Rule 4(c) Report on November 12, 2019. Resp't's Rep.; ECF No. 16. Respondent argued that this case is not appropriate for compensation because the vaccination record indicates that Petitioner received her Tdap vaccine in her left arm, and because the onset of Petitioner's condition is unclear, as she did not seek help from a medical professional until approximately five months after vaccination. *Id.* at 4-6.

After considering litigative risk settlement, Respondent filed a status report on May 4, 2020 indicating that he wanted to defend the case. ECF No. 23. This case was transferred to my docket on May 5, 2020. ECF No. 24.

I held a status conference on May 12, 2020 where I asked the parties whether a ruling on situs and onset or a Rule 5 determination concerning those matters would help to move the case forward. ECF No. 26. On June 11, 2020, the parties requested that I conduct a Rule 5 conference. ECF No. 27. Accordingly, on June 17, 2020, I conducted a Rule 5 conference where I preliminarily found that Petitioner received her Tdap vaccine in her right arm, and that the pain she experienced from that vaccination began the same day. *See* Scheduling Order dated June 18, 2020, ECF No. 28. I ordered Respondent to file a status report indicating how he would like to proceed in light of my preliminary factual determinations. *Id.*

On August 4, 2020, Respondent indicated that he was willing to engage in settlement negotiations. ECF No. 31. The parties attempted to informally resolve the case for approximately ten months. *See* ECF Nos. 32-38. On June 10, 2021, Petitioner indicated her intent to file an expert report due to the lack of progress in settlement discussions. ECF No. 39. Petitioner requested that I rule on the record regarding situs and onset. *Id.* at 2.

Petitioner filed an expert report from Dr. Raymond Peart, an orthopedic surgeon and one of her treating physicians on June 28, 2021. Ex. 23.

On July 12, 2021, Respondent filed a status report indicating that he was amenable to a ruling on the record as to situs and onset. ECF No. 41.

On July 13, 2021, I ordered the parties to file briefs on the factual issues by September 13, 2021. *See* Non-PDF Order dated July 13, 2021. The parties each filed their briefs on September 10, 2021. ECF Nos. 43, 44. This matter is now ripe for a factual determination.

II. Petitioner's Medical Records that Pertain to the Issue of Onset

On November 3, 2017, Petitioner visited the Passport Health Clinic where she received the Hepatitis A and Typhoid vaccinations in her left deltoid. Ex. 3 at 9.

Petitioner received a Tdap vaccine on November 6, 2017. The vaccination record indicates that the vaccine was administered in her left shoulder. Ex. 2 at 1.

On April 16, 2018, Petitioner presented to Dr. Raymond Peart for extremity pain in her right shoulder. Ex. 4 at 10. The medical record indicates that "back in November [Petitioner] went to CVS and had a flu³ vaccine injection...she did have some pain during the actual injection but later that day her shoulder became progressively more painful...she denies having any problems with her right upper extremity..." *Id.* Dr. Peart diagnosed Petitioner with "subacromial bursitis with pain right shoulder status post probable subacromial vaccine injection November 2017." *Id.*

On June 4, 2018, Petitioner visited Anna O'Connor, a physical therapist, for an initial evaluation. Ex. 4 at 7. Ms. O'Connor stated that "[Patient] is starting OP therapy due to right shoulder pain. [S]he had vaccinations in R[ight] shoulder in November 2017 and had severe pain after that." *Id.*

On April 23, 2019, Petitioner visited the Hershey Medical Center due to her ongoing right shoulder pain. The medical record notes that Petitioner "attributes her pain to a vaccination that she received at a local pharmacy." Ex. 13 at 11.

On February 4, 2021, Petitioner had arthroscopic rotator cuff repair and subacromial decompression. Ex. 16 at 85. The clinical note from the operative report indicates: "This is a patient, who has had ongoing pain in her right shoulder following a vaccine injection." *Id.* at 86.

III. Medical Opinion

Dr. Raymond Peart, an orthopedic surgeon and one of Petitioner's treating physicians, provided a letter in support of Petitioner's claim. Ex. 40. In this letter, Dr. Peart opined that Petitioner's injection was likely placed too high on her shoulder due to the fact that she was instructed to pull her shirt down to expose the injection site. *Id.* at 2. This resulted in the needle likely entering the subacromial space. *Id.* Dr. Peart ultimately opined that Petitioner "developed right shoulder pain shortly following a Tdap vaccination consistent with SIRVA." *Id.*

IV. Affidavits that Address the Issue of Onset and Situs

Petitioner filed her affidavit on November 2, 2018. Ex. 1. Petitioner stated that "On November 3, 2017, I received Hepatitis A and Typhoid vaccinations administered into my left shoulder..." *Id.* at ¶ 7. On November 6, 2017, Petitioner "went to CVS Pharmacy...in order to

³ While Dr. Peart states that Petitioner received a flu vaccine in November, the medical records do not indicate that Petitioner received a flu vaccine at this time. Based on the available evidence, I believe Dr. Peart meant the Tdap vaccine Petitioner received on November 6, 2017.

receive a Tdap vaccine.” *Id.* at ¶ 8. Petitioner further stated that “the pharmacist asked me which arm I preferred for the vaccination. I chose my right arm, since 3 days ago, I had received two vaccinations into my left arm.... Within several hours, my right shoulder became sore.” *Id.*

Petitioner filed an affidavit from Ms. Lynda Summy on November 2, 2018. Ex. 11. Ms. Summy stated that “Ms. Strang-Kutay told me that she had received her vaccine the prior day, as planned, but that her right shoulder was ‘killing her.’ Throughout that day, and for several days thereafter, she continued to complain of right shoulder and arm pain and difficulty moving her right arm.” *Id.* at ¶ 7.

Petitioner filed an affidavit from her husband, Gary Kutay. Ex. 10. In this document, Mr. Kutay stated that on November 6, 2017, Petitioner received a Tdap vaccination in preparation for an upcoming trip to Bali. *Id.* at ¶ 6, 7. After she received the vaccine, Petitioner showed Mr. Kutay where the Tdap shot had been injected on the right side, “high on the upper arm”. *Id.* at ¶ 7. Petitioner further stated that “her right arm was more sore than her left arm had been when she had received two vaccinations in the arm several days prior.” *Id.* Petitioner’s right shoulder remained painful after the Tdap vaccination. *Id.* at ¶ 8-12.

Petitioner also filed an affidavit from her daughter, Hollace Kutay. Ex. 9. She stated that on November 6, 2017, she visited a local pharmacy with her mother in order to receive the Tdap vaccine in preparation for an upcoming trip to Bali. *Id.* at ¶ 4. She described that her mother was wearing a business suit, and that the pharmacist instructed her to pull down the collar of her suit in order to expose her right shoulder. *Id.* at ¶ 7. The pharmacist then injected her right shoulder. *Id.* Later that evening, Petitioner told Ms. Kutay that her right shoulder was sore. *Id.* at ¶ 8. Petitioner continued to complain of right shoulder pain in the days and weeks that followed. *Id.* at ¶ 9-12.

V. Legal Standards Regarding Fact Finding

Petitioner bears the burden of establishing her claim by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). A petitioner must offer evidence that leads the “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he or she] may find in favor of the party who has the burden to persuade the judge of the fact’s existence.” *Moberly v. Sec’y of Health & Hum. Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

In order to make a determination concerning factual issues, such as the timing of onset of petitioner’s alleged injury, the special master should first look to the medical records. “Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium.” *Cucuras v. Sec’y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993); *Lowrie v. Sec’y of Health & Hum. Servs.*, No. 03-1585V, 2006 WL 3734216, at *8 (Fed. Cl. Spec. Mstr. Nov. 29, 2006). Medical records created contemporaneously with the events they describe are presumed to be accurate and complete. *Doe/70 v. Sec’y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010).

Contemporaneous medical records generally merit greater evidentiary weight than oral testimony; this is particularly true where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also* *Murphy v. Sec’y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff’d*, 968 F.2d 1226 (Fed. Cir. 1992)(citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) (“It has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight”)). “Written documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later.” *Reusser v. Sec’y of Health & Hum. Servs.*, 28 Fed. Cl. 516, 523 (1993).

However, there are situations in which compelling oral testimony may be more persuasive than written records--for instance in cases where records are found to be incomplete or inaccurate. *Campbell*, 69 Fed. Cl. at 779 (“like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking”); *Lowrie*, 2005 WL 6117475, at *19 (“Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent”) (quoting *Murphy*, 23 Cl. Ct. at 733).

When witness testimony is used to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be “consistent, clear, cogent, and compelling.” *Sanchez v. Sec’y of Health & Hum. Servs.*, No. 11-685V, 2013 WL 1880825 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec’y of Health & Hum. Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person’s failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional’s failure to document everything reported to her or him; (3) a person’s faulty recollection of the events when presenting testimony; or (4) a person’s purposeful recounting of symptoms that did not exist. *La Londe v. Sec’y of Health & Hum. Servs.*, 110 Fed. Cl. 184, 203-04 (2013), *aff’d*, 746 F.3d 1334 (Fed. Cir. 2014). A special master making a determination whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at a hearing must have evidence suggesting the decision was a rational determination. *Burns by Burns v. Sec’y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993).

VI. Findings of Fact

Petitioner has the burden of demonstrating the facts necessary for entitlement to an award by a preponderance of the evidence. § 300aa-12(a)(1)(A). Under that standard, the existence of a fact must be shown to be “more probable than its nonexistence.” *In re Winship*, 397 U.S. 358, 371 (1970) (Harlan, J., concurring).

After reviewing the medical records, expert opinion, and affidavits presented in this case, and after my careful examination of the record as a whole, I find there is preponderant evidence that Petitioner received her Tdap vaccination in her right shoulder, and that the onset of Petitioner’s shoulder pain began on November 6, 2017, the day of vaccination.

A. Situs

Although Petitioner's vaccination record states that she received the Tdap vaccine in her left shoulder, the medical records from April 16, 2017 and June 4, 2017 clearly state that Petitioner sought treatment for her right shoulder due to a vaccination she received in that same shoulder. Ex. 4 at 7, 10. Although more remote in time, Petitioner continued to attribute her right shoulder pain to a vaccination in that same arm. On April 23, 2019, Petitioner described pain in her right shoulder after vaccination. Ex. 13 at 11. Similarly, on February 4, 2021, Petitioner's operative report from her rotator cuff repair notes that Petitioner experienced "ongoing pain in her right shoulder following a vaccine injection." Ex. 16 at 86.

In addition to these medical records, I find the reasoning articulated by Petitioner in her affidavit to be persuasive; specifically, she wanted to receive the Tdap vaccine in her right shoulder because she had recently received two vaccinations in her left shoulder. *See* Ex. 3 at 9; Ex. 1. This reasoning and behavior are consistent with my view of how reasonable people act and lend truth to her claim.

The cumulative weight of these medical records coupled with the persuasive report described in Petitioner's affidavit amount to preponderant evidence that she received her Tdap vaccine in her right shoulder.

B. Onset of Right Shoulder Pain

Petitioner's medical records support a finding that her pain from the Tdap vaccine began within 48 hours of vaccination. On April 16, 2018, Petitioner presented to Dr. Peart for right shoulder pain. Ex. 4 at 10. The medical record indicates that Petitioner experienced pain during the injection itself and "later that day her shoulder became progressively more painful..." *Id.* Although none of the other medical records specifically document onset of pain within 48 hours, they are all consistent with the records from April 16, 2018. *See* Ex. 4 at 7 (an initial PT visit on June 4, 2018 which notes that Petitioner "had vaccinations in R shoulder in November 2017 and had severe pain after that."); Ex. 13 at 11 (medical record where Petitioner "attributes her pain to a vaccination that she received at a local pharmacy."); Ex. 16 at 86 (post-operative report which documents, "This is a patient, who has had ongoing pain in her right shoulder following a vaccine injection.").

In his letter filed in support of Petitioner's claim, Dr. Peart opined that Petitioner "developed right shoulder pain shortly following a Tdap vaccination consistent with SIRVA." Ex. 40 at 2. As one of Petitioner's treating physicians, Dr. Peart's opinion concerning the onset of Petitioner's pain merits due consideration and is a factor in my analysis of the factual issues in this case.

In her affidavit, Petitioner stated that her right shoulder became painful within several hours of her receipt of the Tdap vaccine. Ex. 1 at 2. Petitioner's affidavit as well as those submitted on her behalf provide additional evidence of immediate right shoulder pain after her November 6, 2017 Tdap vaccination.

VII. Conclusion

I have considered Petitioner's medical records, the affidavits submitted by her and on her behalf, as well as Dr. Peart's medical opinion. I find that the totality of this evidence provides preponderant evidence that Petitioner received a Tdap vaccine in her right shoulder, and that she began to experience right shoulder pain on November 6, 2017, the day of vaccination.

The following is therefore ORDERED:

By no later than **December 2, 2021**, the parties shall file a joint status report updating me on their proposed next steps in the case based on the facts articulated in this ruling.

IT IS SO ORDERED.

s/ Katherine E. Oler

Katherine E. Oler
Special Master